

IRBs and Security Research: Myths, Facts and Mission Creep

Simson L. Garfinkel

(slgarfin@nps.edu)

Naval Postgraduate School & Harvard University

April 7, 2008

Abstract

Having decided to focus attention on the “weak link” of human fallibility, a growing number of security researchers are discovering the US Government’s regulations that govern human subject research. This paper discusses those regulations, their application to research on security and usability, and presents strategies for negotiating the Institutional Review Board (IRB) approval process. It argues that a strict interpretation of regulations has the potential to stymie security research.

1 Introduction

As more security researchers turn their attention to usability and other human factors issues, many are surprised to discover that they must comply with regulations governing the use of human beings as experimental subjects.

These regulations, known collectively as “The Common Rule,” were created after a series of well-publicized abuses in the 1960s and 1970s. These regulations require those working with US Government funds to receive approval from their organization’s designated Institutional Review Board (IRB) before most research involving human subjects can commence.

There seems general understanding among researchers that hands-on laboratory usability experiments are covered under the IRB rules. But many other kinds of less-invasive research may still require IRB notification and approval. Furthermore, it appears that many researchers either do not understand their legal obligations, or else have simply chosen to ignore them.

While this paper concerns itself solely with US law, there are “approximately 900 laws, regulations, and guidelines that govern human subjects in 84 countries, as well as from a number of international and regulation organizations”[12]. A list can be found in the reference.

2 Legal Framework

2.1 45 CFR Part 46 Subpart A

The National Research Act (Pub. L. 93-348) created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. This Commission identified a set of ethical principles, and later practical guidelines, for US Government-funded research involving human beings. Ultimately the Department of Health and Human Services wrote and adopted a set of regulations requiring recipients of USG funding to create their own institutional bureaucracies for overseeing re-

search that involves human subjects. These regulations, embodied in Title 45 Part 46 subpart A of the Code of Federal Regulations, exist for one purpose: *to safeguard the welfare of human research subjects*.

Although CFR 45 Part 46 applies only to work funded by HHS, regulations with the same language were adopted in 1991 by 14 other grant-giving USG agencies, including the Department of Defense (DoD), the National Aeronautics and Space Administration (NASA), and the National Science Foundation (NSF). For this reason 45 CFR part 46 subpart A is referred to as “the Common Rule for the protection of human subjects”[13].

2.2 The Institutional Review Board (IRB)

The Common Rule requires organizations performing federally supported research to designate an institutional review board (IRBs) to oversee human subject research. Many organizations fulfill this requirement by establishing their own IRBs. Each IRB must have “at least five members” with different backgrounds so that it can “adequately review [the] research activities commonly conducted by the institution”(§46.107 (a)). Members must include representatives of both genders, at least one scientist and one non-scientist, and one member who is not affiliated with the institution (§46.107(b,c,d)). Members are prohibited from voting on their own research (§46.107(e)).

2.3 IRB Coverage

The Common Rule is very clear: With the exception of six specific categories of research, the Common Rule “applies to all research involving human subjects conducted, supported or otherwise subject to regulation...” (§46.101(a))

Research is defined as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge” (§46.102(d)). *Human Subject* is defined as “a living individual about whom an investigator (whether professional or student) conducting research obtains 1) Data through intervention or interaction with the individual, or 2) Identifiable private information”(§46.102(f)).

The IRB regulations allow organizations to augment the rules, adding requirements, and broadening them to include more areas of research (§46.112). At many schools, including MIT[8], Harvard[11] and UC Berkeley[3], IRB approval is required for *any* research involving human subjects, regardless of funding, and even if the research is exempt under the Common Rule.

Report Documentation Page			Form Approved OMB No. 0704-0188		
Public reporting burden for the collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Washington Headquarters Services, Directorate for Information Operations and Reports, 1215 Jefferson Davis Highway, Suite 1204, Arlington VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to a penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number.					
1. REPORT DATE 07 APR 2008		2. REPORT TYPE		3. DATES COVERED 00-00-2008 to 00-00-2008	
4. TITLE AND SUBTITLE IRBs and Security Research: Myths, Facts and Mission Creep			5a. CONTRACT NUMBER		
			5b. GRANT NUMBER		
			5c. PROGRAM ELEMENT NUMBER		
6. AUTHOR(S)			5d. PROJECT NUMBER		
			5e. TASK NUMBER		
			5f. WORK UNIT NUMBER		
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Naval Postgraduate School, Monterey, CA, 93943			8. PERFORMING ORGANIZATION REPORT NUMBER		
9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)			10. SPONSOR/MONITOR'S ACRONYM(S)		
			11. SPONSOR/MONITOR'S REPORT NUMBER(S)		
12. DISTRIBUTION/AVAILABILITY STATEMENT Approved for public release; distribution unlimited					
13. SUPPLEMENTARY NOTES Usability, Psychology and Security 2008 (Co-located with the 5th USENIX Symposium on Networked Systems Design & Implementation (NSDI '08)), San Francisco, CA. April 2008					
14. ABSTRACT Having decided to focus attention on the 'weak link' of human fallibility, a growing number of security researchers are discovering the US Government's regulations that govern human subject research. This paper discusses those regulations, their application to research on security and usability, and presents strategies for negotiating the Institutional Review Board (IRB) approval process. It argues that a strict interpretation of regulations has the potential to stymie security research.					
15. SUBJECT TERMS					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT Same as Report (SAR)	18. NUMBER OF PAGES 46	19a. NAME OF RESPONSIBLE PERSON
a. REPORT unclassified	b. ABSTRACT unclassified	c. THIS PAGE unclassified			

2.4 IRB Exemptions

The Common Rule contains exemptions for some research involving human beings. For security research the relevant exemptions are:

- Research to be conducted on educational practices or with educational tests (§46.101(b)(1&2)).
- Research involving “existing data, documents, [and] records...” provided that the data set is either “publicly available” or that the subjects “cannot be identified, directly or through identifiers linked to the subjects” (§46.101(b)(4)).
- Research involving “survey procedures, interview procedures or observation of public behavior,” unless information is obtained that could identify the human subjects, and “any disclosure of the response outside the research could place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, or reputation” (§46.101(b)(2)(i&ii)).

Few Organizations allow investigators to decide if their own research is exempt under the guidelines—that would create a conflict-of-interest. For example, Harvard requires that “all research using human subjects” to be “reviewed or designed as exempt from review by a Harvard Institutional Review Board” [11]. In practice, all requests at Harvard to involve human subjects in research goes to a staff member at one of the Harvard IRBs; the staff then decides if the research is actually exempt or in need of review.

2.5 IRB Myths and Facts

Below are some popular myths about IRBs and the Common Rule that are apropos to computer security research.

Myth: Because the Common Rule exempts research involving subjects that cannot be identified, IRB approval is not required when using anonymized data Although this would certainly be convenient, most institutions only allow a determination of exemption to be made by the IRB itself.

Myth: “Pilot studies” do not require IRB approval. Although some schools have policies which define a kind of “pilot study” not requiring IRB approval, there is no support for this interpretation in the Common Rule, which makes no reference to “pilot” or “preliminary” studies.

Many universities (e.g. [15, 9, 4]) have specific language in their IRB guidelines stating that IRB approval is required for *all* research, even pilot studies that will not be published. Georgia State University’s policy [9] goes further, requiring consent forms to indicate if a study is a pilot study and requiring that the experimenter obtain additional IRB approval when the study progresses beyond preliminary stages.

But some organizations allow unapproved pilot studies: the School of Social Service Administration at University of Chicago allows small-scale pilot studies with less than

10 individuals to proceed without IRB approval assuming that “proper steps will be taken to protect human subjects,” sensitive data will not be collected, vulnerable populations will be excluded, and methods with no more than minimal risk will be used. However, SSA/UC requires IRB approval if the data collection in the pilot study will be used in any publication; if the data is to be used, IRB approval is required before data collection begins [5].

Myth: IRB approval is not required if you are working with data you already have. The Common Rule makes no such exception. If previously collected data will be analyzed using a methodology that is different than that which was described in the original IRB application, new approval may be required.

Fact: IRB approval is not required by the Common Rule when using publicly available data. The Common Rule states that research involving the “collection or study” of “existing data, documents [or] records” is exempt “if these sources are publicly available” §46.101(b)(4). But, as previously noted, most institutions require IRB approval for *all work* involving human subjects, even research exempt under the Common Rule.

3 Research Implications

The Common Rule places security researchers in a difficult position: Large quantities of data in our possession or which are easy to get appears to be off-limits for research without prior IRB approval.

3.1 Scenarios

In this section we present seven scenarios of usability & security research projects that potentially use human subject data and which could not have been anticipated when the Common Rule was drafted. We will briefly describe each one; in the following section we’ll discuss whether or not the scenario would require IRB approval.

Scenario 1: Security toolbar with anonymized summary statistics. Alice has developed an anti-phishing toolbar. To assist in development and research, the toolbar sends a small anonymized report to the experimenter once a day. Because each toolbar reports only once every 24 hours, it is easy for the experimenter to measure adoption and use of the toolbar.

Scenario 2: Web server logfile analysis. Bob’s research group operates a popular web-based discussion forum. Bob writes a program which analyzes the web-server’s log file to report the number of daily password resets. He also instruments the software to record the number of newly chosen passwords that do not pass the website’s password complexity rules. The research plan is to see how these numbers change as the rules become successively more restrictive over time. To assure that no personally identifiable information is collected, Bob configures the Apache server so that IP addresses are not logged.

Scenario 3: Popular security search terms. Christine is a graduate student who also writes articles for a major security-related website. She is working on a project that correlates search terms on the website with news stories. The security-related website prepares a report which shows, for each hour, the number of times each term is searched. The report is sent as a PGP-encrypted file to Christine's Gmail account.

Scenario 4: Building better spam filters. Don is creating a better spam filter and wishes to test it on his own inbox.

Scenario 5: Wi-Fi Security Survey. Elaine installs a copy of NetStumbler on a laptop and drives around the neighborhood with a GPS. She compares the names and locations of the Wi-Fi sites with a similar database available online. Her research shows that most of the older Wi-Fi access points that were open are now either closed or have been removed from service. Of the new Wi-Fi access points that have been deployed, most are closed.

Scenario 6: Hidden Data Survey. Guy writes a web crawler and downloads 100,000 Microsoft Word files from public websites. He analyzes the files and finds that approximately 15% contain significant amounts of hidden information. He randomly chooses 100 of the 15,000 files to confirm her software's findings.

Scenario 7: Online EXIFs. Felicity downloads 10,000 JPEGs from a social network website. By examining the camera serial numbers in the images he is able to determine which images were shot by the same camera. She then shows that he can reconstruct the "friends" networks—and shows which pseudonyms are sharing the same camera, indicating that they might be living together or might be the same person.

3.2 Analyzing the Scenarios

Scenarios 1, 2, 3, and 4 clearly require IRB approval under the Common Rule:

1. Alice needs IRB approval because she is recruiting, interacting with, and collecting information from her subjects. Furthermore, her users reveal their IP address when the toolbar reports its statistics; although IP addresses do not necessarily reveal personal information, they frequently do—especially in a university environment where an address may be assigned to a specific person.

2. Even though Bob is not collecting IP addresses, he still needs IRB approval because the information in the webserver logs was generated by human subjects and is not publicly available.

3. Likewise, Christine requires IRB approval because the data is generated by human beings and is not publicly available. Christine could avoid IRB involvement if the security website published the search terms on a public web page rather than encrypting them and sending them to her Gmail account. (Although it seems that this creative

way to bypass the Common Rule has exactly the opposite of the desired effect, presumably the website would do its own privacy audit before releasing such information.)

4. Don has thousands of legitimate and spam messages, but the Common Rule prohibits him from analyzing incoming email without IRB approval.

The other scenarios are more troublesome:

5. Elaine might not require IRB approval for his survey because she is not observing people: She is observing wireless access points. But these devices were configured (or not configured) by people. And in some rural areas the GPS coordinates might identify specific individuals.

6. Guy's research with Word documents literally involves "existing ... documents" that are "publicly available," so it should be exempt under the Common Rule. But the documents might have been inadvertently placed on the Internet and contain private information.

7. Felicity's research, like Guy's, probably does not fall under the Common Rule if she only collects documents (e.g., the photographs) that are publicly available. But what if the images were available to a large community but not the general public?

3.3 Researcher's Can't Say "Trust me"

Although researchers might be frustrated by the conclusions of this analysis, it is important to realize that the Common Rule is doing precisely what Congress intended when it passed the National Research Act: Congress wanted to put a stop to scientists saying "trust me." For decades, scientists had argued that good scientific practice and ordinary research ethics would protect the interests of their subjects. Experience proved otherwise.

With the National Research Act, Congress concluded that some scientists were not worthy of trust when it came to evaluating the impact of their own experiments on experimental subjects. And with good reason: some research involving human beings frequently requires deception, stress, or bodily risk. The Act recognizes that it is sometimes unreasonable to ask a scientist to be both an advocate for their research and their research subjects well-being.

For example, Alice could data mine her logfiles, seek out the personally identifiable IP addresses, perform Google searches to correlate IP addresses with email addresses, and then create a web page that identifies people who have "good" security practices (because they run her program) and "bad" practices (because they uninstalled her program.) Perhaps she might even send phishing attacks to the subjects to see how they respond. The IRB structure provides a place for someone who has had training to review her research protocol.

There are many ways to "anonymize" log files: sometimes the anonymization is incomplete and personally identifiable information can be recovered. One reason to require IRB review of research involving "anonymized"

logs is so that a neutral third-party can review protocol. Otherwise, we are just trusting the good judgement of the researcher—a person who has an inherent conflict-of-interest.

The analysis in Don’s case seems silly: after all, Don already has the email messages, and they were voluntarily sent to him by his friends and colleagues. But those people didn’t send Don the email for the purpose of being involved in an experiment. Part of the IRB process is to protect human beings who are involved in research without their knowledge or consent.

Since each of the scenarios above involve no more than minimal risk, we believe that an IRB would properly approve each protocol under the Common Rule’s “expedited review procedures” (§46.110). At many organizations the expedited review involves a form that is submitted by email and is administratively approved within days by either the IRB chair or a staff member. Although it appears to be a formality, expedited review has an important role: it forces the experimenter to create a written description of the research protocol. The mere act of writing down the protocol and discussing it with the IRB may help the experimenter to realize ways to further minimize the impact of the experiment on the human participants.

3.4 The Human Test

One useful test of the need to involve an IRB is to ask this question: *would the experiment be useful if the data were generated by a random process and not by a human?* For scenarios #2 and #3 above, the answer would clearly be “no.” The only reason that our hypothetical Bob is interested in reviewing password rule violations, and Christine is interested in search terms is precisely because this information is being generated by human subjects. If the passwords and search terms were randomly chosen, the research would not be worth doing.

If the experiment can be performed with randomly generated data, then use random data. This is an application of the “respect for persons”[2] ethical principle.

4 Working with the IRB

It is widely believed that different IRBs apply different standards when deciding whether or not to approve computer security research. This is likely a result of IRBs having different levels of experience with this kind of research.

We suggest several approaches that security researchers can take to improve the situation with their IRBs:

- Researchers should be intimately familiar with both the Common Rule and whatever local regulations their home institutions may have adopted.
- Researchers must learn how to make clear and cogent arguments that their research should be approved under the “expedited review procedures” on

the grounds that there is “minimal risk” to the experimental subjects.

- IRBs have the authority to waive informed consent requirements (§46.116(c,d)). Researchers should become familiar with this option and request it where appropriate.
- Researchers should be familiar with protocols that have been approved by other IRBs. The research community would also benefit from having an open repository of approved protocols.
- Security researchers should volunteer to serve on their organization’s IRBs. Bringing security expertise to the IRBs in this manner will help educate other IRB members and ease the way for other security research involving human subjects. (We have heard stories of IRBs that have blocked membership of computer scientists on the grounds that they were not biomedical researchers and the position on the IRB reserved for a non-scientist was already taken. Such positions are a misreading of the Common Rule, which specifies minimums but not maximums of IRB membership (§46.107)).

5 IRB “Mission Creep”

IRBs are centers of power: they have the ability to shut down research, and they operate with little institutional supervision. There are also complaints that IRBs have become more restrictive, in some cases acting as if their purpose is to safeguard their institutions from lawsuit, rather than to protect the welfare of experimental subjects. Perhaps as a result, some researchers have complained of a pervasive IRB “Mission Creep,” in which more and more research is being placed under the purview of IRBs.

In November 2005 the Center for Advanced Study at the University of Illinois College of Law held a conference on the topic of “IRB mission creep” and produced a 32 page paper, based on a two-year study, stating that IRBs were being stretched thin by being forced to pay excessive attention to research that poses little chance of risk. The report also called for “removing some kinds of activity from IRB review altogether,” especially journalism and ethnography[1]. The authors later published an editorial in *Science* making many of the same claims[10].

Journalism is particularly a problem, the Illinois group argued, because people who are the subject of journalistic research are frequently injured by the results. The example they give is that of President Richard Nixon, whose reputation was damaged and who lost his job as the result of the Watergate investigation. Although this research had great social value, it might not have been permitted by an IRB.

Katz argues that the Common Rule turns ethnographers into “IRB Outlaws” when they perform fieldwork by living with a host community to learn about it. The very

premise of field work is that results cannot be predicted, so it is impossible to get approval in advance from an IRB for what might happen[14]. Recently an entire issue of *American Ethnologist* was devoted to this topic[7].

A growing number of observers have criticized IRBs for being research censorship instruments. Cohen writes that an IRB that he sat on, which was primarily comprised of health care professionals, “received a qualitative, social science project to review. The IRB promptly disapproved it because it wasn’t science in the view of the IRB members”[6]. The protocol was eventually approved, but only after Cohen convinced the IRB to send the proposal out for external review.

6 Conclusion

Some might say that this call for IRB involvement in computer security research is part of IRB Mission Creep. But the Common Rule, as written, clearly applies to much work in the field of usability, psychology and security.

The problem here is that the Common Rule was written to cover biomedical and psychological research. It is clear that the authors never imagined a day that not just researchers, but most members of our society would have desktop computers containing personal information created by thousands of individuals with whom we have no direct relationship.

The penalties for performing research without approval include forced termination of research and loss of funding: we ignore the rules at our own peril. But in the long term, society would be better served with broader exemptions that could be automatically applied by researchers without going to an IRB.

Revisions to the Common Rule should also address a particularly wasteful practice: the intentional destruction of data which was collected without IRB approval: this practice certainly seems to violate the Belmont Report’s “respect for persons” principle.

The Common Rule was created because of abuses in medical and psychological research, but the Rule was very broadly written. If it cannot be revised or reinterpreted, the impact on computer security research may be severe.

7 Acknowledgements

This paper is partially funded by Naval Postgraduate School’s Research Initiation Program.

Brent Olde and Amelia Weinreb both provided useful insights in the preparation of this paper. Craig Martell, James Migletz, Beth Rosenberg and Adam Slagell all provided important feedback. Drafts of this paper were reviewed by Associate Professor Paul Ohm at University of Colorado Law School and by James M. Miller, an SAIC senior policy, program and legal analyst.

The author has worked with IRBs at MIT, Harvard and NPS; the author is currently a member of the NPS IRB.

References

- [1] Deb Aronson. *Improving the System for Protecting Human Subjects: Conteracting IRB “Mission Creep”*. Technical report, College of Law, College of Liberal Arts and Sciences, Office of the Vice Chancellor for Research, November 2005. <http://www.law.uiuc.edu/conferences/whitepaper/whitepaper.pdf>.
- [2] The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. *Ethical Principles and Guidelines for the protection of human subjects of research*, April 18 1979.
- [3] *Research Compliance: A Faculty Handbook*, 2008. Accessed January 2008, <http://rac.berkeley.edu/compliancebook/humansubjects.html>.
- [4] *Frequently Asked Questions*, January 2008. Accessed January 2008, http://www.capella.edu/portal/alumni/scontent/resources/research_center/FAQ.aspx.
- [5] *Does your study need IRB review?*, 2007. Accessed January 2008, <http://www.ssa.uchicago.edu/ssairb/doesyourstudy.shtml>.
- [6] Jeffrey Cohen. *IRB Expertise*, 2 October 2007. <http://hrpp.blogspot.com/2007/10/irb-expertise.html>.
- [7] *American Ethnologist*, Virginia R. Dominguez (Ed.). <http://www.aesonline.org/ae/334>.
- [8] MIT Committee on the Uses of Humans as Experimental Subjects. *COUHES Overview*, 2003. <http://web.mit.edu/committees/couhes/index.shtml>.
- [9] *Frequently Asked Questions*, January 2008. Georgia State University. Accessed January 2008, <http://www.gsu.edu/research/irb-faq.html>.
- [10] C. K. Gunsalus, Edward M. Bruner, Nicholas C. Burbules, Leon Dash *et al.* *Mission Creep in the IRB World*. *Science*, volume 312(5779):(2006) page 1441. <http://www.sciencemag.org/cgi/content/summary/312/5779/1441>.
- [11] *Approvals and Certifications*, 2008. http://vpf-web.harvard.edu/osr/proposal/prop_pr.certifications.shtml.
- [12] Office for Human Research Protections. *International Compilation of Human Research Protections*, 2008. <http://www.hhs.gov/ohrp/international/HSPCompilation.pdf>.
- [13] United States Department of Health and Human Services. *Federal Policy for the Protection of Human Subjects*, 2008. Accessed January 2008.
- [14] Jack Katz. *Ethical Escape Routes for Underground Ethnographers*, 2008. Unpublished draft, <http://www.sscnet.ucla.edu/soc/faculty/katz/pubs/UndergroundEthnographersDraft.pdf>.
- [15] *Student Research*, May 2007. UCSF School of Medicine. <http://medschool.ucsf.edu/studentresearch/irbpolicy.aspx>.

IRBs and Security Research: Myths, Facts and Mission Creep

Simson L. Garfinkel

- Center for Research on Computation an Society
- Naval Postgraduate School



Since the late 1990s, security researchers have increasingly focused on "the weakest link."

As computers became more connected, they became less secure.
This, despite:

- Revolution in cryptography (RSA & faster CPUs)
- Java (no buffer overflows)
- 20+ years of secure operating system research.

Why? Most operational security problems result from *human factors*:

- User error (failure to use cryptography; improper use)
- Configuration error
- Programmer error
- Specification error
- Poorly understood problem

Human factors dominate today's security landscape.

Phishing, Wireless Security, Sanitization Failures

If we want to make real improvements, we need to see *where* and *why* people are making errors, and then either:

- *train the people so they don't make errors*
- *fix the software so that training is not required.*

We can't do this without working with **human subjects** or **data from humans**.

This brings us under Federal Regulations and the IRB structure.



Why do we have IRBs?

(Institutional Review Boards)

A lot of scientists did a lot of bad things in the 1960s.

- "Tuskegee Study of Untreated Syphilis in the Negro Male" (1932-1972)
- Stanley Milgram shock psychology experiments (1961; 1974)
- Timothy Leary LSD experiments at Harvard (1961)
- Stanford Prison Experiment (1971)



Results:

- National Research Act (PL 93-348) signed into law July 12, 1974
- National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1974-1978)
- The Belmont Report ("Ethical Principles and Guidelines for the Protection of Human Subjects of Research," April 18, 1979)

1979: The Belmont Report's key findings

1. Respect for Persons

- "Individuals should be treated as autonomous agents"
- "Persons with diminished autonomy are entitled to protection."

2. Beneficence

- "Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being"
- "Do not harm"
- "Maximize possible benefits and minimize possible harms."

3. Justice

- Fairness in distribution of the results of the research.

<http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm>



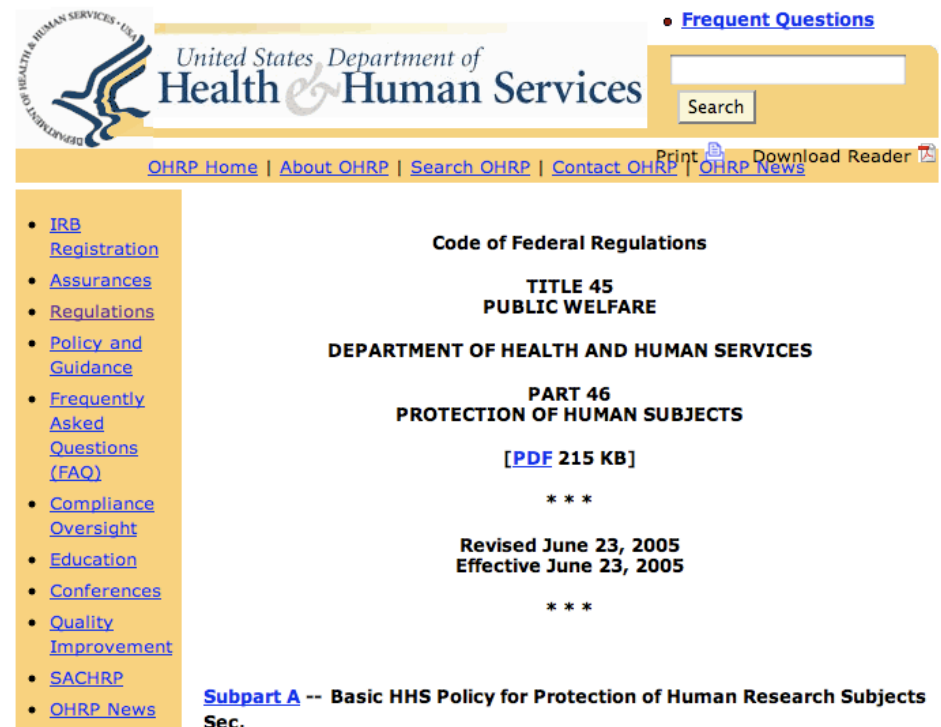
45 CFR 46: The Common Rule (1991)

Originally adopted by HHS to govern use of humans in research.

Adopted by other federal agencies in 1991 (EPA's is 40 CFR 26)

Applies to:

Agency for International Development
Consumer Product Safety Commission
Department of Agriculture
Department of Commerce
Department of Defense
Department of Education
Department of Energy
Department of Health and Human Services
Centers for Disease Control
Food and Drug Administration
National Institutes of Health
Department of Housing and Urban Development
Department of Justice
Department of Veterans Affairs
Department of Transportation
Environmental Protection Agency
National Aeronautics and Space Administration
National Science Foundation



United States Department of Health & Human Services

Code of Federal Regulations

TITLE 45
PUBLIC WELFARE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

PART 46
PROTECTION OF HUMAN SUBJECTS

[PDF 215 KB]

Revised June 23, 2005
Effective June 23, 2005

Subpart A -- Basic HHS Policy for Protection of Human Research Subjects Sec.

- [IRB Registration](#)
- [Assurances](#)
- [Regulations](#)
- [Policy and Guidance](#)
- [Frequently Asked Questions \(FAQ\)](#)
- [Compliance Oversight](#)
- [Education](#)
- [Conferences](#)
- [Quality Improvement](#)
- [SACHP](#)
- [OHRP News](#)

[Frequent Questions](#)

Search

Print Download Reader

[OHRP Home](#) | [About OHRP](#) | [Search OHRP](#) | [Contact OHRP](#) | [OHRP News](#)

In addition, the Central Intelligence Agency and Social Security Administration are required by Executive Order and statute, respectively, to follow the DHHS regulations (including all subparts).

45 CFR 46 has very broad definitions for "Research" and "Human Subjects"

Research:

- "systematic investigation including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."
- "whether or not they are conducted or supported under a program which is considered research for other purposes."

Human subject:

- "A living individual about whom an investigator (whether a professional or student) conducting research obtains"
 - (1) Data through intervention or interaction with the individual, or
 - (2) Identifiable private information

Enforcement through the Institutional Review Board.

Each organization receiving Federal research funds must designate an Institutional Review Board (IRB)

At least five members:

- "**Varying backgrounds** to promote complete and adequate review of research activities commonly conducted by the institution."
- "**Diversity**:" race, gender, cultural backgrounds
- Assures compliance with "**institutional commitments** and **regulations**, applicable **law**, and **standards** of professional conduct and practice"
- Both **genders**
- At least **one scientist**
- At least one person **not otherwise affiliated** with the institution

The IRB has very broad powers.

- IRB approval is required before work involving human subjects can **commence**.
- IRB decides if application can be "**expedited**."

The IRB has no jurisdiction over research that is exempt or not federally funded:

- Research on educational practices or with educational tests
- Research involving "existing data, documents, [and] records" (provided data is "publicly available" or subjects "cannot be identified".)
- Research involving surveys or interviews, unless results could identify the humans **and** place subjects at risk of "criminal or civil liability."

Nevertheless, most organizations require that **all** work involving human subjects go through IRB review.

What is "IRB Approval"?

IRBs have several ways of "approving" research.

The IRB can:

- **EXEMPT** — Declare research does not require IRB approval.
- **EXPEDITE** — Approve as "minimal risk" without a review by the full IRB.
- **APPROVE WITH FULL REVIEW**

From the point of view of a Computer Security researcher, all of these require:

- Notifying the IRB
- Submitting *something* (email, application, etc)
- Getting a response.

Even "EXEMPT" research require some kind of involvement and approval.

Myth or Fact?

Because the Common Rule exempts research involving subjects that cannot be identified, IRB approval is not required when using anonymized data.

Myth or Fact?

Because the Common Rule exempts research involving subjects that cannot be identified, IRB approval is not required when using anonymized data.

Myth

This would be convenient, but most institutions require the determination to be made by the IRB.

Myth or Fact?

"Pilot studies" do not require IRB approval.

Myth or Fact?

"Pilot studies" do not require IRB approval.

Myth

The common rule makes no reference to "pilot" or "preliminary" studies.

Most policies I reviewed have require IRB approval for all research.

Myth or Fact?

IRB approval is not required if you are working with data that you already have.

Myth or Fact?

IRB approval is not required if you are working with data that you already have.

Myth

IRB approval is for a specific experimental protocol.

Minor changes in protocol may be granted "expedited" review.

Myth or Fact?

IRB approval is not required when using publicly available data.

Myth or Fact?

IRB approval is not required when using publicly available data.

Fact!

The Common Rule exempts research with "publicly available" records.

Myth or Fact?

IRB approval is not required when using publicly available data.

Fact!

The Common Rule exempts research with "publicly available" records.

But most institutions (Harvard, NPS, UC) still require IRB review!

What does IRB approval require?

Administrative overhead for the application:

- What is the protocol?
- What human subjects are involved?



Respect for the human subjects:

- Will the subjects be informed? If so, how? If not, why not?
- What specifically will the subjects be told?
- How will their information be protected?

Social Justice:

- How are the subjects recruited?
- Who will benefit from the research?

For many computer [security] researchers, IRB regulations are a an unexpected complication.

Much of today's research involves use of computers by people.

- User interface work.
- Applications (email, web)
- Operating systems (file systems)
- Programming languages

Much of the data on computers was generated by people:

- email messages
- Program samples

A surprising number of experiments that you can imagine doing with data you already have is probably covered by IRB regulations.

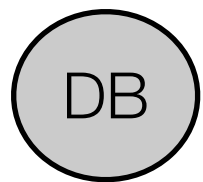
Scenario 1: Security toolbar with anonymized summary statistics.



Alice has developed an anti-phishing toolbar.

To assist in development and research, the toolbar sends a small anonymized report to the experimenter once a day.

Because each toolbar reports only once every 24 hours, it is easy for the experimenter to measure adoption and use of the toolbar.



Alice needs IRB approval



Alice is:

- Recruiting subjects.
- Interacting with her subjects.
- Collecting information from her subjects.

Furthermore:

- Alice's users reveal their IP address when the toolbar reports its statistics.
- IP addresses do not necessarily reveal personal information, but they frequently do.
- The European Union considers IP addresses to be PII.
- At Harvard, IP addresses are frequently assigned to a specific person.

Scenario 2: Web server logfile analysis.



Bob's research group operates a popular web-based discussion forum.

Bob:

- Analyzes the server's log file to report # of password resets each day.
- Records # of new passwords that do not pass password quality rules.
- Web server does not collect IP address.

Research question: how do restrictive rules affect password resets?

At least 3 letters and 2 numbers

UPPERCASE and lowercase

2 digits and 3 symbols (*&^%\$#)

big letters and small letters

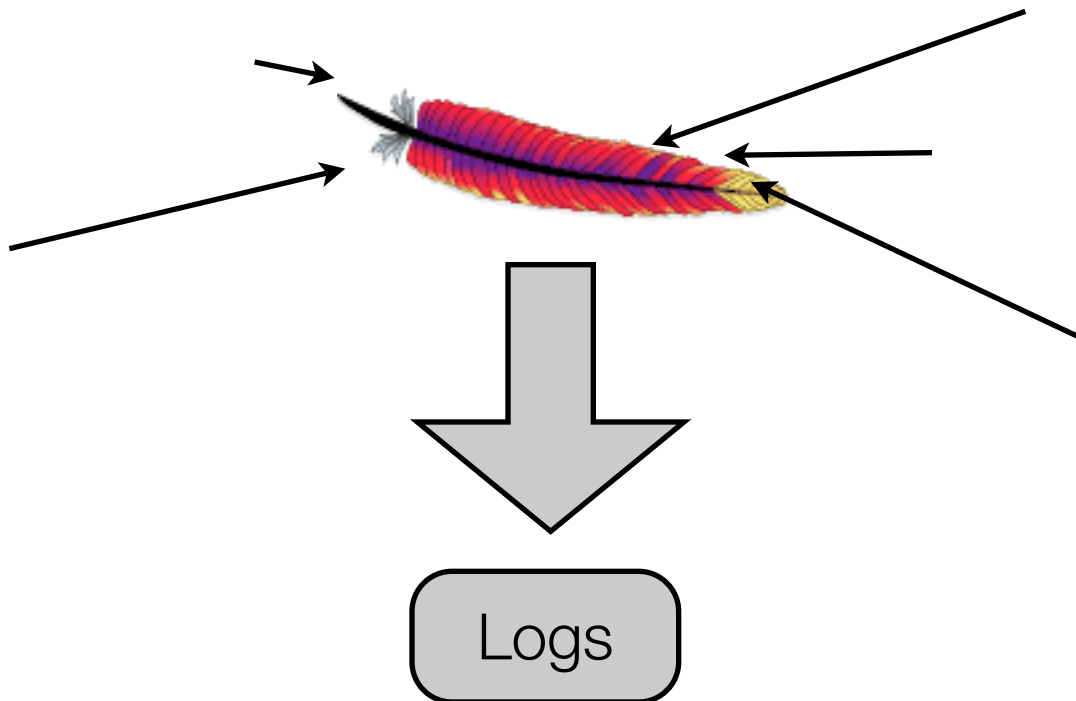
At least 3 different colors

Bob needs IRB approval.



Bob is not collecting IP addresses!

But Bob needs IRB approval because the information in the webserver logs was generated by human subjects and is not publicly available.



Scenario 3: Popular security search terms.

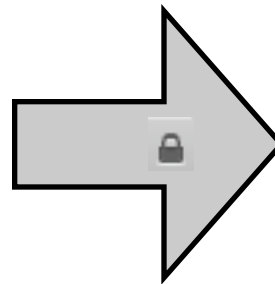


Christine is a graduate student who also writes articles for a major security-related website.

Christine is working on a project that correlates search terms on the website with news stories.

The security-related website prepares a report which shows, for each hour, the number of times each term is searched.

The report is sent as a PGP-encrypted file to Christine's Gmail account.



+Search Terms

Christine needs IRB approval!



The data is generated by human beings and is not publicly available.

Christine could avoid IRB involvement if:

- The website published the search results on a public web page (rather than protecting the information and controlling its release.)

and

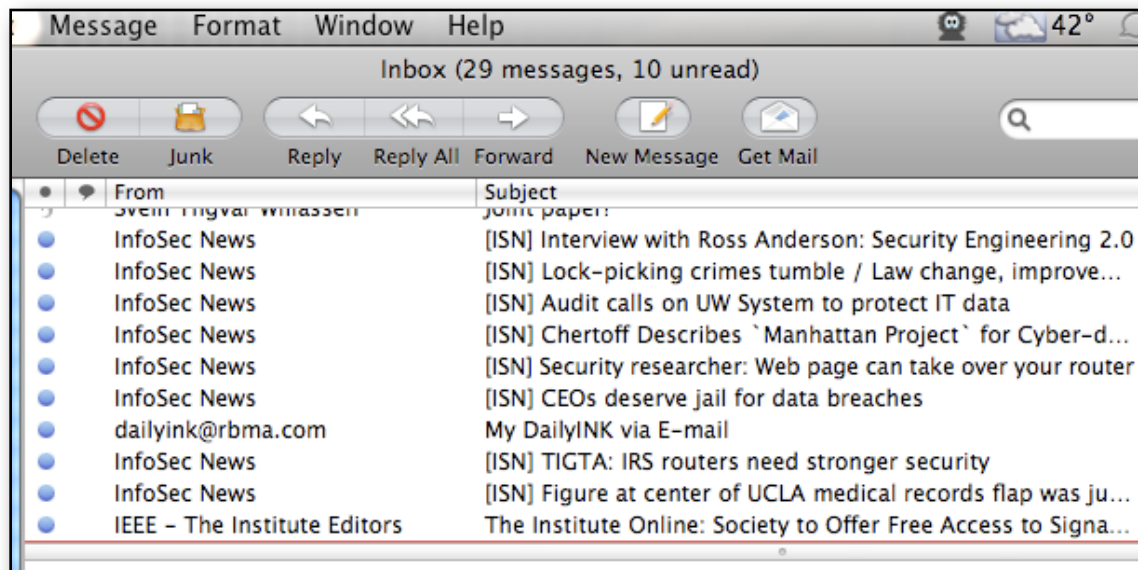
- If Christine is at an institution that does not require IRB approval for exempt work.

Alternatively, Christine can avoid the IRB if she does the study for the website without using Federal research funds.

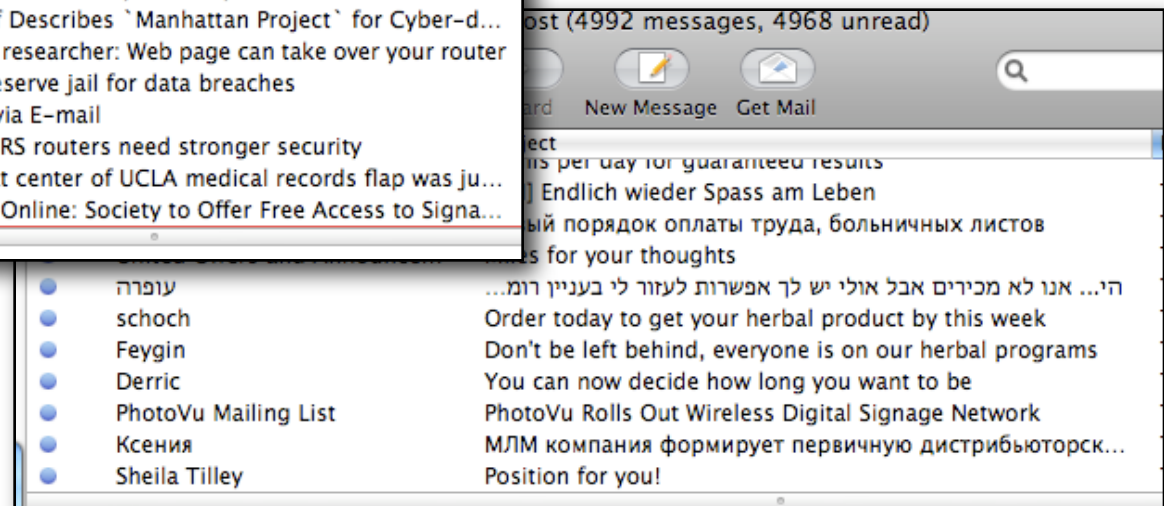
Scenario 4: Building better spam filters.



Don is creating a better spam filter. He wants to test it on his inbox.



Not Spam



Spam

Don needs IRB approval!



Common Rule does not exempt information already in Don's possession.

RESPECT: The people who sent mail to Don did not consent for their email to be used in the experiment.

PROTECTION OF SUBJECTS:

- Who sent Don email? Why?
- Is there confidential information in Don's inbox?
- What procedures did Don follow to make sure that there will be **minimal risk** for the people who sent him mail?

Scenario 5: Wi-Fi Security Survey

Elaine installs NetStumber on a laptop and drives around the neighborhood with a GPS.

Elaine compares names & locations of Wi-Fi sites she finds with an online database.

Research results:

- Older Wi-Fi access points that were open are now closed or have been removed from service.
- Newer Wi-Fi access points are closed.



Elaine might not require IRB approval,
but she might.

Elaine is not observing people, she is observing APs

- But they were configured by people.
- The names might be identifiable.
- The GPS coordinates might be identifiable.



Scenario #6: Hidden Data Survey



Frank downloads 100,000 Microsoft Word files from public websites.

15% of the files contain significant amounts of hidden information.

Guy randomly chooses 100 of the 15,000 files and confirms the findings.

many of these sources, their credibility was difficult to assess and was often left to the foreign government services to judge. Intelligence Community HUMINT efforts against a closed society like Iraq prior to Operation Iraqi Freedom were hobbled by the Intelligence Community's dependence on having an official U.S. presence in-country to mount clandestine HUMINT collection efforts.

(U) When UN inspectors departed Iraq, the placement of HUMINT agents and the development of unilateral sources inside Iraq were not top priorities for the Intelligence Community. The Intelligence Community did not have a single HUMINT source collecting against Iraq's weapons of mass destruction programs in Iraq after 1998. The Intelligence Community appears to have decided that the difficulty and risks inherent in developing sources or inserting operations officers into Iraq outweighed the potential benefits. The Committee found no evidence that a lack of resources significantly prevented the Intelligence Community from developing sources or inserting operations officers into Iraq.

When Committee staff asked why the CIA had not considered placing a CIA officer in Iraq years before Operation Iraqi Freedom to investigate Iraq's weapons of mass destruction programs, a CIA officer said, "because it's very hard to sustain . . . it takes a rare officer who can go in . . . and survive scrutiny for a long time." The Committee agrees that such operations are difficult and dangerous, but they should be within the norm of the CIA's activities and capabilities. Senior CIA officials have repeatedly told the Committee that a significant increase in funding and personnel will be required to enable the CIA to penetrate difficult HUMINT targets similar to prewar Iraq. The Committee believes, however, that if an officer willing and able to take such an assignment really is "rare" at the CIA, the problem is less a question of resources than a need for dramatic changes in a risk averse corporate culture.

(U) Problems with the Intelligence Community's HUMINT efforts were also evident in the Intelligence Community's handling of Iraq's alleged efforts to acquire uranium from Niger. The Committee does not fault the CIA for exploiting the access enjoyed by the spouse of a CIA employee traveling to Niger. The Committee believes, however, that it is unfortunate, considering the significant resources available to the CIA, that this was the only option available. Given the nature of rapidly evolving global threats such as terrorism and the proliferation of weapons and weapons technology, the Intelligence Community must develop means to quickly respond to fleeting collection opportunities outside the Community's established operating areas. The Committee also found other problems with the Intelligence Community's follow-up on the

Frank doesn't need IRB approval under the Common Rule!



The research is exempt!

- The word files are "existing ... documents" that are "publicly available."
- **Even though the information may be confidential!**
- **Even though the information may be leaked without the author's knowledge!**

(Of course, if Frank is at Harvard he still needs IRB approval.)

Scenario #7: Online EXIFs



Gail downloads 10,000 JPEGs from a social network website.

By examining the camera serial numbers in the images she is able to determine which images were shot by the same camera.

Felicity shows:

- She can reconstruct "friends" networks.
- She can find pseudonyms sharing the same camera.

Are these the same people?

Or people living together?

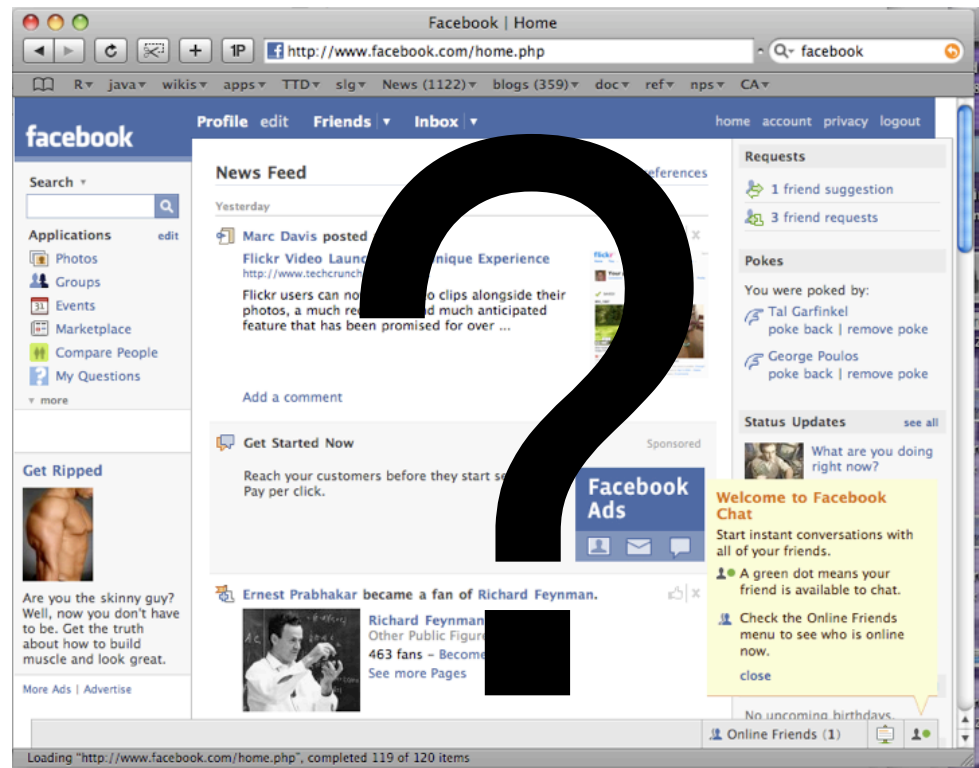


Gail probably doesn't need IRB approval either.



The documents (photographs) are publicly available.

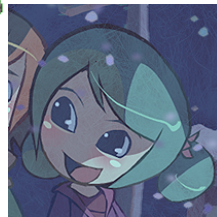
- But what if the website requires registration?



Trust me!

Can we trust these researchers to do the right thing?

- Alice: anti-phishing toolbar
- Bob: Web server logfile analysis (bad passwords)
- Christine: popular security search terms
- Don: better spam filters
- Elaine: Wi-Fi Security
- Frank: hidden data survey
- Gail: EXIF analysis



We got the National Research Act

because researchers in the 1960s said "trust me" and they were wrong.

Research can blind the researcher to the needs of the research subjects.

Each researcher has access to sensitive data that could be misused.

The IRB process forces the researchers to:

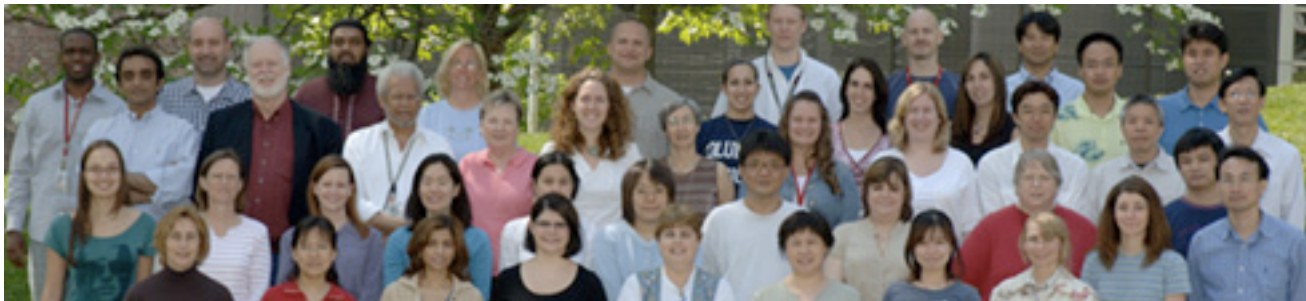
- Document what they are going to do.
- Think about how human subject data will be protected.
- Treat the human subjects with respect.

These scenarios involve no more than "minimal risk" and should be approved under the Common Rule's "expedited review" procedure.

The Human Test

"Would the experiment be useful if the data were generated by simulation or random processes and not by a human?"

- If YES, then ***don't use humans!*** (Respect for persons)
- If NO, then ***get IRB approval!*** (Follow the law.)





Advice for working with IRBs

Be intimately familiar with the Common Rule and your local regulations.

Make clear arguments that research should be approved under "expedited review procedures."

Ask your IRB to waive informed consent requirements (§46.116(c,d)).

Be familiar with protocols that other IRBs have approved.

Security researchers should volunteer to serve on their organization's IRBs.

IRB Mission Creep

IRBs are being applied to more areas of research:

- Oral histories.
- Ethnography
- Journalism



Some IRBs are quite conservative:

- Some IRBs are protecting the institution, rather than enforcing the rules.
- Some IRB members refuse to approve studies that they think "aren't science."

Retroactive approval question:

- How do you "wash" data that was collected w/o IRB approval?

IRB Resources

NSF FAQ — advocates consent forms in plain language, not legalese

- <http://www.nsf.gov/bfa/dias/policy/hsfaqs.jsp>

"Mission Creep in the IRB World," *Science* 9 June 2006, vol. 312

"The Wrong Rules for Social Science," *The Chronicle of Higher Education*, March 9, 2001

"Ethical Escape Routes for Underground Ethnographers," Jack Katz, UCLA, working paper